

MEDICAL RECORD	MINOR PATIENT'S ASSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY • Attach to NIH-2514-2, Consent to Participate in a Clinical Research Study
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INSTITUTE: National Institute of Child Health and Human Development

STUDY NUMBER: 97-CH-0076 PRINCIPAL INVESTIGATOR: Constantine A. Stratakis, M.D.

STUDY TITLE: Tumors of the Pituitary Gland and Associated Conditions: A Genetic Investigation

Latest IRB Review: Continuing Review 2/4/04

Latest Amendment Approved: Amend D 1/12/03

Assent Form 2

Your parents have brought you to the National Institutes of Health, because you have a tumor in a part of the body called the "pituitary gland". We do not know what caused this tumor.

Read this paper and ask us questions about anything you do not understand. Then you and your parents decide if you wish to take part.

What we want to do

We want to find what caused your tumor, and whether this tumor can happen again in another person in your family.

We will ask you to come to our hospital at the National Institutes of Health (NIH). We will need to find out what kind of tumor you have. In order to do this, we may need to do some blood and urine tests and get X-rays of parts of your body.

We will also do a test that was not done by your doctor: We will collect blood to get a substance called "DNA". DNA is the substance that contains the genes, that decides what runs in families ("inheritance"). Our DNA has all the information for how we look, and what diseases we may have. We will compare your DNA with that of your parents, brothers and sisters to see if there is anything about your genes that may be causing your tumor.

What we want you to do

(1) Your parents and/or your pediatrician will need to tell us about any medical problems you may have. Anything they tell us will be kept private.

(2) We will ask you to spend a number of days (usually, no more than two weeks) in the hospital to do the tests to find out what kind of tumor you have.

(3) We will need to examine your blood. To get your blood, we will stick a needle into your arm and take a small amount of blood (2 to 4 teaspoons) through the needle. That will only hurt for a minute. Then it will stop hurting. We will put a special cream on your arm called EMLA, one hour before drawing blood to help blood drawing so that it doesn't hurt as much. A small plastic tube will remain in your arm and blood will be taken from it, so that we do not need to use a needle every time blood is taken from you.

(4) We may need to do some special blood tests to find out what kind of tumor you have. These will be explained to you and your parents.

PATIENT IDENTIFICATION	MINOR PATIENT'S ASSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY NIH-2514-2 (4-97) P.A.: 09-25-0099 File in Section 4: Protocol Consent (4)
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MEDICAL RECORD**CONTINUATION SHEET for either:**

NIH 2514-1, Consent to Participate in A Clinical Research Study

NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study

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(5) We would like to obtain a small piece of the tumor that will be taken out at the NIH for DNA and other experiments. Most, or all, of the tumor will be used to identify what type of tumor you had; only, if the tumor is big enough, we will take one or two pieces for laboratory experiments or for storage.

(6) We may need to take pictures of parts of your body, with the help of machines that we have in the hospital ("Department of Radiology"). In one of these tests (called "MRI-scan") you will be on a moving bed, and your body will be surrounded by a big tube. That will only last for about 30 minutes, but you will need to lie still for the time that the test lasts. The space inside the tube is very small; if you are frightened by it, someone can stay in the room and talk to you. Also the machine normally makes a loud ticking noise that may surprise you. We may need to do the MRI-scan twice, but if you do not want us to do this test for a second time please let us know and we will not do it.

(7) We may take photographs of you in your underwear, that we will use in the future to look at the way you change as you grow.

(8) Everything we find out will be explained to you and your parents. We will also find out if you have any other diseases or tumors. If your pituitary tumor needs to be removed, we will tell you, your parents and your doctor. If you and your parents want, this surgery will be done here at the NIH, and another doctor (the surgeon) will explain to you and your family about the surgery. If medicine is needed, we will discuss it with you and your family. If other treatment is needed that cannot be offered at the NIH, we will discuss with you and your parents where and how this treatment can be done. For example, "radiation" treatment is something that can be done for you but we can not do it here at the NIH (under this study).

(9) If you have a disease called (Cushing Syndrome) we may ask you to answer some questions and write your answers. These questions will ask you about any behavior changes that you may have experienced because of Cushing Syndrome. All the information that you will provide will be kept private with the exception of information that may be considered by the doctors dangerous to yourselves or to others; the answers to these questions, may be reported to your parents or your doctors.

(10) A total of nine tests will be administered and their completion takes about three hours – they will be explained to you with every detail by your parents and the doctors that will help you in their completion. We will also ask you to have another MRI, like the one we described to you above. It will take approximately 3 hours to complete the tests and 30-45 minutes to have the additional MRI. You do not have to take these tests, if you do not want to. These tests will need to be completed twice: once before the surgery and once every year for five years after the surgery.

What you have to decide about

We want you to understand what we will do, why we do it, and the things that will hurt. Ask us if there is anything you do not understand now or later.

If you agree to come to the hospital, be seen by our doctors and have blood tests, and the other tests needed to study your tumor, we will ask you to write your name on this piece of paper, beside the X. Writing your name here is the way of showing that you agree.

PATIENT IDENTIFICATION**CONTINUATION SHEET for either:**

NIH-2514-1 (10-84)

NIH-2514-2 (10-84)

P.A.: 09-25-0099

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You do not have to do this, if you, or your parents do not want to. Do not write your name until you feel you understand what will happen. Even if you agree now, you and your parents can change your minds later. Just tell us that you do not wish to take part any longer.

I have had this study explained to me in a way that I understand, and I have had the chance to ask questions. I agree to take part in this study.

Signature of Minor Patient: _____ Date: _____

Signature of Investigator: _____ Date: _____